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GMC's guidance may inhibit research

Citation for published version:

Leslie, SJ & Webb, DJ 2001, 'GMC's guidance may inhibit research', *British Medical Journal (BMJ)*, vol. 322, no. 7302, pp. 1601-2. <https://doi.org/10.1136/bmj.322.7302.1601>

Digital Object Identifier (DOI):

[10.1136/bmj.322.7302.1601](https://doi.org/10.1136/bmj.322.7302.1601)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Publisher's PDF, also known as Version of record

Published In:

British Medical Journal (BMJ)

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Letters

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GMC: approaching the abyss

Preservation is well worth the effort

EDITOR—In his editorial on the General Medical Council, Smith asks a question that is in danger of becoming a self fulfilling prophecy.¹ He fairly describes differences of view in the British medical profession about governance and the introduction of revalidation. He then asks whether it is worth expending the effort required to ensure the GMC's survival on the grounds of its being dysfunctional, even suggesting that it might be better to scrap it and start again.

We write as a disparate group of senior doctors who have been intimately involved in the debate on the future of the GMC. We have held differing views about the solutions that might be offered but are united on the over-riding importance of professionally led regulation in partnership with the public. In this, we concur with Smith that most doctors wish to practise to the highest possible standards and that the model of the intrusive regulatory scrutiny practised by casino operators is totally inappropriate to the medical profession.

We believe, from very different perspectives, that the GMC should be allowed to develop into a better organisation for doctors and, more importantly, for patients.

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Smith's implication that we should start looking at fresh alternatives begs the question as to who would be entrusted to do this work and whether the result would be any better equipped for the challenges faced by a 21st century regulator in an increasingly complicated society. Any "fresh start" would still have to deal with governance and revalidation, which have been firmly placed on the current agenda by the present GMC.

The abyss Smith describes is certainly there, and the GMC may be at its edge. Despite its current problems, however, the GMC is the crucible of our professionalism and without it doctors in this country would become mere technicians.

Any alternative to professionally led regulation is unthinkable.

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Dr Keighley receives an honorarium as a medical screener.

1 Smith R. GMC: approaching the abyss. *BMJ* 2001;322:1196. (19 May.)

People should be wary of the alternative

EDITOR—As lay members of the General Medical Council, we know that we have a particular responsibility to discharge properly the GMC's first duty: the protection of the public. We are in no doubt that all members of the council—medical and lay, elected and appointed—strive hard to ensure that patient wellbeing is at the forefront of their work in standard setting, education, and registration, as well as in the fitness to practise procedures. Equally, we support the major reforms now under way to ensure that the GMC's processes and values remain in tune both with rapidly changing medical knowledge and practice and with society's expectations in a new century.

Radical change is uncomfortable, and the present debate reflects this, but it is

essentially about means, not ends. Smith asked whether the GMC is worth saving or should be replaced by some other form of regulation altogether.¹ The only other alternative to professionally led regulation seems to be a licensing and inspection system run by government. Experience in other professions and in other countries suggests that this would be demotivating for doctors and much more expensive to operate. In addition, it could produce conflicts of interest as full determination of standards and quality and responsibility for the organisation and resourcing of health become vested in the same body.

As patients and carers, we want our doctors to be governed by their consciences as well as their contracts. As lay members of the public active in the GMC, we are well aware of the many hours put in by doctors on a largely unpaid basis. We are convinced that the active involvement of practising doctors in all the council's functions is crucial in keeping it up to date and maintaining the trust and support of both the public and the profession.

The key requirement is to make the GMC fit for a purpose so that it retains professional support while meeting the legitimate expectations of the public. We think that the changes currently in train, while capable of some adjustment, must be carried through to ensure that the GMC provides an environment in which doctors continue to enjoy the trust of the public.² Medical regulation through the GMC with its growing partnership of medical and lay members remains the best way of "protecting patients and guiding doctors"; any other mechanism really could be a step into the abyss.

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1 Smith R. GMC: approaching the abyss. *BMJ* 2001;322:1196. (19 May.)

2 Ferriman A. Poll shows public still has trust in doctors. *BMJ* 2001;322:694. (24 March.)

GMC: keeping feet on firm ground

EDITOR—Smith queries the functions of the General Medical Council in the new heavily regulated era for medicine.¹ Coordinating the medical schools, constructing the profession's ethical code, and setting baseline professional standards, are three of them and would not be done more appropriately by the state or its agencies. Professional

regulation (not self regulation) to protect the public requires a strong partnership between lay and medical representatives. Many doctors still think that choosing, through elections, the doctors on the regulatory body is better than any alternative.

Smith concludes that the GMC is failing. Before seeking fresh alternatives, as he suggests, many members of the Academy of Medical Royal Colleges are currently working hard to seek agreements to the two main issues of governance and revalidation.

Looking over an abyss can be one way of learning how important it is to keep your feet on firm ground.

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1 Smith R. GMC: approaching the abyss. *BMJ* 2001;322:196. (19 May.)

Time to go

EDITOR—It is time for the General Medical Council to go.¹ With the possible exception of its health committee, it has a long history of being draconian, of incompetence, and of poor leadership. Its slogan, "Protecting patients, guiding doctors," reflects typically muddled bifocal thinking.

There is no future in revalidation. There is no instrument that will effectively detect a dysfunctional doctor with any degree of reliability until the doctor makes a mistake, when it becomes too late. It has to be ultimate folly to believe that doctors, apparently unlike any other professional, will willingly report failures and faults themselves. It is equal folly to assume that fellow workers will have the time, energy, or motivation to be watchdog and reporter.

The only solution for the GMC is disbandment. The work of the health committee has been of sufficient quality and standard as to be replaced by an equal.

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1 Smith R. GMC: approaching the abyss. *BMJ* 2001;322:1196. (19 May.)

Australia may show way forward for the United Kingdom

EDITOR—It seems to be common ground that regulation of the profession by the General Medical Council is better than an alternative, state run, system.¹ Ultimately, the argument concerns the power of the GMC or some other body to suspend or strike off a practitioner. Perhaps this is a false choice.

No doctor should be deprived of the ability to earn a livelihood other than as a consequence of due process when an alleged, serious misdemeanour has been investigated and proved. If that belief is shared by all, then the question is whether or not a body, constituted as is the GMC, in its present or any alternative form, is an appropriate body to execute such justice. There is always a risk of its being perceived as biased,

either towards a favoured son or against a thorn in the side of the establishment.

One of the former British colonies resolved this problem many years ago. In New South Wales the powers of the medical board do not include suspension or deregistration. The Medical Practice Act gives this power to the medical tribunal. This comprises a judge of the district court; two medical practitioners appointed by the Medical Board from panels nominated by the colleges, the universities, the Department of Health, and the Australian Medical Association; and a lay person chosen from a panel nominated by the Minister for Health.

The medical board itself makes no adverse decisions about any doctor, other than about eligibility for initial registration. All inquiries that might have an adverse outcome for a doctor's right to practise are conducted by committees that are independent of the board but governed by the Medical Practice Act.

Might this help the debate in the United Kingdom?

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1 Smith R. GMC: approaching the abyss. *BMJ* 2001;322:1196. (19 May.)

Assessing clinical competence and revalidation of clinicians

Simulated surgeries would have advantages

EDITOR—McKinley et al present cogent arguments for directly assessing the consultation competence of general practitioners undergoing revalidation.¹ They identify the required attributes of an assessment as reliability, validity, acceptability, feasibility, and educational impact. They do not mention, however, that the methodology must also be capable of setting a consistent standard for pass/fail decisions for every candidate.

The model that they offer depends on the judgment of two observers watching 10 consecutive consultations, a task that they might undertake 12 times in a year. If the prevalence of insufficient competence was 2% they might encounter it once every four years. How could they apply a minimum standard reliably, along with their 1000 assessor colleagues? Just 10 randomly presenting cases will be too few to guarantee an adequate coverage of consultation skills, and in the absence of standardisation it will be hard to achieve a reliability score above 0.5. Furthermore, the patients will behave differently if they know that their doctor is under assessment, thus compromising validity.

The 12 case simulated surgery for the MRCGP (membership of the Royal College of General Practitioners) examination is a model that would overcome these difficulties. The cases are written to test specific skills; the patients are role players who are

trained to present the same challenge to each candidate; each examiner observes the same case throughout the circuit and marks the candidate's performance on a predetermined schedule; each candidate is assessed by all 12 examiners, which minimises bias; and the pass mark is set by the aggregation of the judgments of all the examiners, based on the cases they have marked.

This examination has yielded reliability figures (coefficient α) in excess of 0.8 in all six administrations over three years. Face validity is high ("like a locum surgery"), and content validity is controlled. The method is acceptable (universally preferred to video by eligible candidates). The cost is less than £350 per candidate if the circuits are full. A profile of skill subscores can be presented to the candidate, providing formative feedback. If the administration was put in place, regular simulated surgeries could be offered for revalidation in regional venues throughout the United Kingdom.

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1 McKinley RK, Fraser RC, Baker R. Model for directly assessing and improving clinical competence and performance in revalidation of clinicians. *BMJ* 2001;322:712-5. (24 March.)

Video assessments might be effective screening method

EDITOR—McKinley et al have shown the reliability and feasibility of their consultation assessment for examining consultations in general practice, but they have glossed over some issues.¹

The first such issue is the desirability of an assessment that tries to be both formative and summative. Trying to do both at the same time is generally accepted to be problematic.² Although an assessment method may be valid when used in both ways, the stress of undertaking a summative assessment may affect performance adversely. The idea that the five attributes of assessment are multiplicative is not a true mathematical concept, and the absence of one does not negate the others. A summative assessment does not have to have educational impact after the assessment: its impact is in setting the learning aims and objectives for learning before assessment.

The second issue is that of patient acceptability. The authors raise the problem that certain types of patients decline to be videoed, but it might be expected that the same patients will decline to have two strangers sitting in the consultation. Videoing can be intrusive, but around three quarters of patients forget the camera during the consultation.³ It is far harder to forget two extra people.

The third issue is reliability. The table on bmj.com shows high figures for the validity, but the number of observers who were involved is not clear. Increasing the number of observers is likely to decrease the inter-observer reliability.

The summative assessment video component may only have inter-rater reliability

that is "not impressive," but its reliability in screening poor performers is reckoned to be 95%, these then undergoing further assessment.⁴ If the purpose of the exercise is to select out underperforming general practitioners then a similar tool would be effective, and possibly cheaper as a screening method. The problem of finding enough assessors remains.

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Authors' reply

EDITOR—Burrows advocates the simulated surgery used during the MRCCGP (membership of the Royal College of General Practitioners) examination as a potential tool for assessing consultation competence for revalidation.¹ Although this approach has some commendable features (for example, a guaranteed range of clinical challenges), we have previously questioned its credibility, let alone validity.²

Burrows admits that the simulated surgery for the MRCCGP examination does not test ability to make diagnoses or to elicit abnormal physical signs. Surely both are fundamental skills for all clinicians. The marking system is also peer referenced and not criterion referenced, which is essential for equity in regulatory assessments.

We can reassure both Burrows and Gravestock about the reliability that can be achieved with multiple assessors. We have reported a study of the assessment of the consultation competence of 180 medical students involving 86 trained assessors, most of whom assessed fewer than five students. The interassessor reliability of pass/fail decisions was 0.94.³

This high level has been replicated in regulatory assessments of over 140 general practice registrars in Kuwait, again involving multiple pairs of assessors, both internal and external (paper in preparation). With minimal screening, 10 patients provided sufficient clinical challenges. These data confirm that assessments such as we propose can be highly reliable when performed by multiple assessors.

Gravestock asserts that summative assessment need not have educational impact and, consequently, that the five essential attributes of an assessment instrument are not truly multiplicative. All candidates can benefit from explicit feedback on how to improve, and those who fail have a right to be informed why the assessors reached their judgment. This is particularly essential when the livelihood of a professional colleague is at stake. It is widely accepted by leading medical educa-

tionalists that the essential attributes are indeed multiplicative.⁴ Incidentally, all assessments can be stressful irrespective of methodology—this is a fact of life.

We agree with Gravestock that patient acceptability is important. Indeed, we emphasised this in our paper. Over 8000 patients have participated in our assessment studies in Leicestershire,³ Kuwait, and Hong Kong, and all these involved the presence of two assessors in the consulting room. The circumstances are fully explained to patients, whose consent is mandatory. There have been few refusals and no adverse comment by the patients.

The authors of both these letters support our contention that assessing clinical competence through direct observation must be central to the revalidation of clinicians. Like them, we do not underestimate the logistical implications. Nevertheless, the profession needs to get on with the task.

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Results from pilot study using portfolio and 360° questionnaire

EDITOR—Regular appraisal of consultants is to become an integral part of the new NHS.¹ McKinley et al addressed the problems inherent in the process.² We present the initial results of a pilot study of appraisal using a portfolio and incorporating a 360° approach.

The project included 20 consultants, who completed a portfolio based on the General Medical Council's guidelines for revalidation.³ A 360° appraisal questionnaire was distributed by each consultant to 10 team members and 20 patients; it was based on the American Board of Internal Medicine validated questionnaire and had questions on attitude, communication, and skills.³ The return rate for patients was 50% and that for team members 84%.

No problems were reported with completing the portfolio questionnaire, and consultants had no problem with job plans, including both NHS and independent practice. The only sections impossible to complete concerned critical incidents and complaints. Currently, this information is not collected centrally in our trust. The median score for all consultants for both the team and patients was in the very good or excellent category. This was reassuring. Participants thought, however, that the

distribution of questionnaires to patients and team members should be random and handled centrally. The anonymity of replies was considered to be crucial.

The broadest spread of replies came from clinicians with primary care responsibilities rather than those in service specialties. Scoring was consistent for individual clinicians, with the same spread seen in all questions. Comments from consultants shown the overall results of team and patient questionnaires varied from complimentary to outright rejection.

The time taken to undertake this pilot study in only 20 consultants was 40 hours and 2000 pieces of paper. A large institution with 500 consultants would need 1000 hours and 50 000 pieces of paper, as well as 2500 hours to conduct appraisal (a minimum of 5 hours per consultant, including preparation)—716 consultant sessions.

We conclude therefore that appraisal by portfolio and 360° assessment is feasible if properly funded. Further work is necessary to simplify the assessment of team and patient perception. Emphasis must be placed on minimising the time spent to reduce the impact on service delivery. If the process is handled sympathetically and with common sense, however, it will be a benefit to all.

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GMC's guidance may inhibit research

EDITOR—Academic clinical research, including the evaluation of new treatments, is central to providing high quality, cost effective care to patients, and it requires the cooperation and goodwill of the patients who volunteer to participate. The research process is externally regulated and monitored by ethics committees to ensure that patients are protected.

We welcome the debate on the Data Protection Act and access to patients' records,¹⁻³ and wish to raise a related concern about the General Medical Council's recent guidelines on confidentiality and their effect on research.⁴ The GMC's document focuses on patients' rights to confidentiality and the protection of personal information. Guidance is important to protect both patients and doctors, and we recognise the value of consent in sharing confidential information.

In clinical research it is now clear that the physician within a healthcare team who

is responsible for a patient's care "must be satisfied that patients have been told, or have had access to written material informing them, that their records may be disclosed to persons outside the team" and "that they have the right to object."¹ The only exception is where obtaining consent is not practicable or "where the benefits to an individual or to society ... outweigh the public and the patient's interest."²

Presumably the public interest will rarely outweigh a patient's rights and it will, therefore, be the responsibility of individual investigators and practitioners to ensure that compliance with guidance occurs. Because of the new guidance, difficulties may arise between healthcare teams within hospitals and between hospitals and general practices. Previously, for instance, a hospital team interested in investigating a new treatment for a condition that was mainly seen by general practitioners might have used records from the practice to identify patients to whom the general practitioner could then write. However, this would contravene the GMC's current guidance, and alternative strategies have major implications for resources. In a general practice with links to several hospital research projects it might be sensible to ask all patients whether they would be willing to be approached, but this would be costly and take time.

These issues will need to be addressed if the NHS is to remain committed to such research, and we believe that addressing these issues is in the best long term interest of both patients and doctors. Nevertheless, we are concerned that there has been little response to the GMC's document and that the current position inhibits clinical studies that might improve patient care.

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Optimising management of delirium

Placebo controlled trials of pharmacological treatments are needed

EDITOR—In reviewing the management of delirium, Meagher asserts that antipsychotic drugs are effective in patients with delirium.¹ There is, however, little evidence to support this assertion. There are no placebo controlled trials of antipsychotic drugs in patients with delirium. One trial compared antipsychotic drugs with benzodiazepines and found that antipsychotic drugs were superior, but, given that it is widely acknowledged that

benzodiazepines may worsen delirium, this result hardly constitutes evidence of efficacy.² Most clinicians have gained the impression that antipsychotic drugs speed recovery in delirium, but their anecdotal observations must be doubted. Most episodes of delirium last only several days and will improve when the patient's underlying medical condition resolves. In practice, medical management is always instituted simultaneously with prescription of antipsychotic drugs. As a consequence, it would be very difficult for clinicians to isolate the relative effect of an antipsychotic drug on the resolution of delirium. Uncontrolled trials suggesting efficacy will present the same problems.

Delirium often manifests with hallucinations, delusions, or thought disorder. In other psychiatric disorders, such as schizophrenia, these symptoms are improved by antipsychotic drugs, so it is reasonable to postulate that these drugs may also help in cases of delirium. But this hypothesis may be invalid. Treatments for asthma will not necessarily help pneumonia, although both illnesses cause shortness of breath. With so little evidence to support the use of antipsychotic drugs in patients with delirium, management strategies invoking them must be extremely cautious. Meagher proposes a strategy for the management of severe behavioural disturbance in patients with delirium that could quickly lead to doses of haloperidol of up to 100 mg per day. Doses this high may be associated with anticholinergic toxicity and akathisia—a sense of inner restlessness—that may worsen agitation rather than quell it. Such doses also entail an increased risk of torsades de pointes and the neuroleptic malignant syndrome.^{3,4}

Moreover, if the analogy with schizophrenia is valid, it is unlikely that patients would benefit from more than 12 mg of haloperidol per day.⁵ Antipsychotic drugs should be avoided until all non-pharmacological management options are exhausted. If they are to be used, haloperidol is the drug of choice, but doses should not exceed 12 mg per day. If pharmacological management of behavioural disturbance is required after this, then benzodiazepines should be used, with the understanding that gaining control of the behavioural disturbance may involve an unavoidable perpetuation of the delirium that is driving disturbance. Obviously, there is an urgent need for placebo controlled trials.

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Patients with delirium should be treated with care

EDITOR—With respect to Meagher's review of delirium and its management we would like to raise a cautionary note.¹ Measures that protect vulnerable (often elderly) people from the appearance of delirium, such as good nursing care and the provision of an appropriate ward environment, are always preferable to sedation with psychotropic medication of those who have developed the condition. Every medical and nursing student is taught the basic strategies to be used in managing a delirious individual that Meagher reviews, yet a visit to any busy medical ward shows that such principles are often forgotten in the face of shortages of skilled nurses, rapid discharge of patients, and harassed junior medical staff.

Chemical restraint of delirious patients should never be used as a substitute for simple nursing care. When medication has to be used, because of the hazards associated with psychotropic drugs, doses should be kept to an absolute minimum. Traditionally, haloperidol has been the mainstay of such treatment, and in our experience doses at the absolute lower end of those suggested by Meagher—for example, haloperidol 0.5-1.0 mg—are sufficient for effective control of agitated behaviour in delirium. As old age psychiatrists, we are surprised and disturbed by the high doses of haloperidol suggested in the article for the pharmacological treatment of severe disturbance in delirium, since most of those who will be treated are elderly. If one followed the treatment plan suggested, then this could involve giving up to 30 mg haloperidol intravenously within 30 minutes and repeating this in the following 30 minutes, with the worryingly reassuring message that up to 100 mg intravenous haloperidol every 24 hours is generally safe.

These doses may be suitable for the acute management of young patients with functional psychoses who exhibit disturbed or violent behaviour to which one of the references cited in support of this regimen pertains,² but should not be taken as a guide in elderly medically ill or cognitively impaired individuals. Two thirds of patients with delirium have an underlying dementia and 20% of dementia patients have dementia with Lewy bodies.³ Hence, at least 10% of all cases of delirium will have dementia with Lewy bodies, and since this is characterised by exquisite sensitivity to neuroleptics,⁴ this represents a further need for extreme caution in management.

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Author's reply

EDITOR—These letters highlight the difficulties in attempting to control for the many factors that influence outcome in treatment studies of a complex neuropsychiatric disorder of multifactorial aetiology. The situation in patients with delirium is further complicated by the issue of consent. In the absence of controlled studies, the best available evidence supports the contention that the use of typical antipsychotic drugs is associated with rapid resolution of delirium in most patients that is evident before the impact of medical interventions, is independent of sedative actions, and correlates with alterations in measures of monoamine metabolism.¹ Although Ryan thinks that most cases of delirium will rapidly resolve regardless of whether antipsychotic agents are used, accumulating evidence indicates that this is a misconception and thus provides support for more aggressive treatment of these patients.² Nevertheless, controlled studies would help clarify the impact of antipsychotic agents in the management of delirium.

The theoretical basis for the use of antipsychotic agents extends beyond the observation of symptomatic overlap with functional psychoses and derives from preclinical and clinical observations regarding the neurochemical disturbances that relate to delirium.³ Direct extrapolation from observations that relate to patients with schizophrenia, for example, should be made with caution.

The letters also draw attention to some of the risks of using haloperidol. Partly as a consequence of the inactivity that has characterised the field of delirium, drug treatment of delirious patients typically involves non-licensed use of psychotropic drugs. Appropriate doses for delirium management have not been established, but caution is required in prescribing for patients with concomitant problems that confer a greater susceptibility to adverse effects from antipsychotic agents. The review emphasises the importance of non-pharmacological approaches to treatment and advocates haloperidol at low doses as the most appropriate treatment where pharmacotherapy is deemed necessary. In addition, the problem of management of highly disturbed patients in intensive treatment settings with potentially life threatening levels of behavioural disturbance is addressed. The management of elderly patients with suspected Lewy body dementia, a condition characterised by neuroleptic intolerance, would be expected to differ considerably, and, according to preliminary evidence, procholinergic

agents may be a useful option in these cases.⁴ Clinicians should consider the relative benefits and risks of treatment with haloperidol at high doses versus the not inconsiderable risks of uncontrolled disturbance in severely ill delirious patients, which include death. The available literature indicates that high doses of haloperidol have been used with therapeutic success in such situations.⁵ The management of this small number of extremely challenging cases should not be confused with the routine management of patients with delirium.

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Competing interests: None declared.

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Withdrawal of Droleptan (droperidol)

EDITOR—Droperidol is a drug used by psychiatrists for its sedative and antipsychotic effects. It is also, however, a widely used and highly effective antiemetic when used at low doses for both the prevention and treatment of postoperative nausea and vomiting.^{1,3} It has a very good side effect profile at these doses.² It is also a drug that is commonly used in combination with morphine for patient controlled analgesia, where it has consistently been shown to reduce the incidence of opiate induced nausea and vomiting.⁴ A recent review suggests that it is the only antiemetic with any evidence of efficacy in those circumstances.⁵

It surprised us therefore to learn that Janssen-Cilag withdrew this useful drug on 31 March 2001. We appreciate that there may be a problem with the chronic usage of this drug in a psychiatric setting, the concerns being about the potential effect of droperidol on the cardiac QT interval. We find it hard to believe that this makes it unviable for Janssen-Cilag to continue to produce the injectable preparation for its perioperative uses, given its presence in most anaesthesia rooms. In this setting, the small doses used and the short term administration of the drug make it unlikely that the same problems would occur as in continuous treatment with high doses.

We understand that an assessment of the risks and benefits assessment has been carried out, which led Janssen-Cilag to withdraw droperidol voluntarily, but we seriously doubt whether its short term, low dose use was included in this. Janssen-Cilag is the sole manufacturer of branded droperidol, and

we are unaware of any generic alternative. It is likely that when supplies become exhausted soon after the withdrawal date we will have to turn to more expensive alternatives with its consequences for the national drug bill.

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Competing interests: None declared.

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Animal research

Journal editors could help raise profile of three Rs of animal research

EDITOR—The RSPCA (Royal Society for the Protection of Cruelty to Animals) believes that the use of laboratory animals presents an ethical dilemma that affects everyone. Animals are used for a broad range of purposes, and thus it is not possible or constructive to make sweeping statements about scientific validity, justification, or suffering. Issues subject to such polarised debate are inevitably difficult to resolve. In this case, sentient animals capable of suffering are involved.

The human race has a moral imperative to reduce the pain, suffering, and distress that it inflicts on other animals to an absolute minimum. In the case of animal experiments, the principle of the three Rs—replacement, reduction, refinement—is an excellent practical starting point, and the RSPCA is committed to promoting and supporting it. Greater consideration is now given to implementing this concept, but it is not universally applied (or understood), and much is still to be achieved. One likely reason for this is that the three Rs are often seen as a separate issue and not part of mainstream life sciences.

One way to raise the profile of the three Rs, and push for them to pervade the whole of the life sciences, would be for journal editors to insist that published papers include comprehensive information about the lifetime experiences of the animals involved. This could include their source, transport, husbandry and care, group sizes and structure, enrichment, what was actually done to the animals, protocol refinements, welfare problems (and what was done about them), and the animals' eventual fate (and why).

Journal space is at a premium, but it is possible to convey this information in surprisingly few words.^{2,3} Such detail would provide guidance for other researchers wishing to improve animal welfare and reduce suffering, as well as giving other interested parties an insight into what laboratory animals actually experience and why. This would help to depolarise the debate and enable people with an interest to contribute to it in an informed and constructive way.

Although the *BMJ* rarely publishes animal research, perhaps it would consider this kind of comprehensive editorial policy to help steer the debate towards the middle ground so that it can go further, faster.

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Ethics committees have influenced animal experiments in Sweden

EDITOR—The debate in the United Kingdom on animal research¹ and the impending Home Office review of the system² prompted us to scrutinise the influence that ethics committees have had on animal experimentation in Sweden.

In Sweden the review of animal experimentation by animal ethics committees was made compulsory in July 1979. Until 1998 the decisions of the seven regional committees were advisory; after that date they became regulatory. Scientists may, if their application is rejected, appeal to a higher court.

We analysed whether and how the committees have approved the applications subject to minor changes. We explored the main reasons for these conditions and how their frequency varied over time by analysing protocols from the meetings of three ethics committees (Jan 1989-Sept 2000). Altogether 10 432 applications were processed: 7895 were approved, 1907 were

approved with modifications, 427 were postponed, 105 were rejected, and the applicants withdrew 98. Some applications required more than one modification before approval. The table shows how the modifications to project applications that were required by the ethics committees before approval may be grouped.

The frequency of modifications required by the ethics committees varied over the years from 10% to 30% (overall average 18%). The three year moving average showed an increasing trend from 16% to 29% during 1999 and 2000. This may reflect a media debate during this period on the ethics committees' role, which was initiated by a government investigation.³

The areas that the ethics committees focused on has varied with time. In recent years pain relief and ensuring the presence of a licensed supervisor seem to have received increasing attention, whereas the interest in introducing earlier humane end points seems to be decreasing.

About three quarters of the modifications may be categorised as refinement with respect to animal welfare, and the modifications requested have had a positive influence on project designs. The systems in the United Kingdom and Sweden cannot, however, be directly compared. The Home Office Inspectorate has played an active and professional part in the United Kingdom in improving project applications through dialogue with individual applicants. The introduction of ethics committees in the United Kingdom might simply result in this important activity being moved from the inspectorate to being a responsibility of an ethics committee.

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Three Rs should be registration, randomisation, and reviews (systematic)

EDITOR—Having found no reliable evidence from human clinical research about how much fluid should be given in the resuscitation of bleeding trauma patients, I am working with others on a systematic review of controlled trials of fluid replacement in animal models.¹ To date we have identified about 70 controlled trials.

Some trials are properly randomised but many are not. The potential for selective publication of trials showing more promising treatment effects is considerable, and few if any of the trials set their results in the context of a systematic review of all previous trials. Reducing bias is as important in animal research as in clinical research, and it

would seem appropriate to apply the strategies used to improve the quality of clinical research to improve animal research. I therefore propose the following three Rs of animal research:

- Registration: prospective registration of all trials in animals to reduce the potential for publication bias
- Randomisation: proper randomisation to reduce the potential for selection bias
- Reviews: systematic reviews to reduce bias and increase precision.

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Would middle ground approach give "added value"?

EDITOR—Forty years ago, before animal rights militancy had driven animal research behind a wall of secrecy, the University of Manchester invited an antivivisection group to tour its animal research laboratories and meet the research scientists. My friend, an animal rights activist with a highly polarised viewpoint, was determined to confront these "animal torturers." When he returned he was, surprisingly, full of praise for the researchers.

He admired the university's courage in opening its laboratory doors and facing frank discussion with "the enemy." He found that the researchers, far from being the crazed animal torturers of his imagination, were reasonable and caring. They accepted proposals that the animal rights group put forward for improvements in the quality of life of the laboratory animals, and a follow up visit confirmed progress.

Aggression projected on to this animal research laboratory was unsustainable once a cooperative relationship had been established. When I drew attention to the turnaround in my friend's views he rationalised it by saying, "I haven't changed my mind about animal research. This laboratory is different from the others—it genuinely cares about its animals."

Was this laboratory different from others? Perhaps it was, because it invested in communication and contact rather than condemnation and distance, or perhaps because it took a long and sensitive look at its activities in relation to the prevailing sentiment in society. A common pitfall for animal experimentation is that familiarity breeds contempt. I have encountered very caring doctors, scientists, and vets who became inured over time to what they were doing to sentient creatures in the name of medical or veterinary research.

Both sides of the animal research debate regale us with visions of how good life could be for humans or animals if we would just give them a free hand. Both sides are willing to torment, maim, and kill, as required. How many of these visions are fantasies, I wonder? How many are worth the price that society may have to pay?

Reasons for modification requested by ethics committee 1989-2000

Modification requested by committee	No
Improvement of project design	442
Improvement of euthanasia method	212
Limiting animal number	201
Improved anaesthesia	198
Improved animal housing/husbandry	188
Earlier end point, general	187
Earlier end point, specific	156
Lack of licences/informed consent	137
Ensure licensed supervisor present	102
Improved pain relief	86
Formal errors in application	70
Other	37
Consult veterinarian	11
Total	2027

We need visions to further our quality of life, including the vision of living harmoniously with other creatures. Should our society facilitate all the visions that people seek to promulgate? If not, how can we weed out those that are about ignorance, personal ambition, projected emotions, or commercial greed?

All sectors of society have a part to play. I have proposed a model for such cooperation in the welfare of farm animals that could easily be extended to medical research (www.pighealth.com).

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More funding must go towards finding alternative non-animal methods

EDITOR—Throughout the recent, highly emotive debate regarding animal experimentation and the fate of the medical research firm Huntingdon Life Sciences¹ one crucial factor has been ignored—namely, the importance of non-animal alternative methods. The Fund for the Replacement of Animals in Medical Experiments (FRAME) is a charity that funds research into the development of alternative methods that do not require the use of animals. We were pleased to see Smith's editorial, which acknowledged the crucial role that alternative methods can have in bringing about a reduction in the use of animals in research and testing.²

British and European law dictates that animals can be used only when no non-animal alternative is available. The development of reliable alternative methods is the best way of achieving the fund's ultimate goal of eliminating the need for live animal experiments.

Current levels of funding for research into alternative methods are disappointing. If the government wants the decline in the number of tests on animals to continue then this funding must be dramatically increased. As well as the government, the industries that currently rely on animal research to develop and market their products could support this research into non-animal methods. The Fund for the Replacement of Animals in Medical Experiments would like to see the industries putting considerably more of their resources into developing alternative methods.

The development and validation of non-animal methods is long and expensive. The rewards, though, are potentially great in terms of the benefits to science and to animal welfare.

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1 MacDonald R. How animal passions became aroused. *BMJ* 2001;322:244. (27 January.)

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Various fallacies persist in vivisection debate

EDITOR—MacDonald might not have produced such a favourable review of Croce's book on the ethics of experimenting on animals had she had the time and inclination to research his claims that animal research is scientifically flawed.¹

Thalidomide was never tested in pregnant animals before its use in patients. After the first publication describing fetal abnormalities in babies whose mothers had taken thalidomide during pregnancy the drug was shown to be teratogenic in rats, mice, hamsters, rabbits, and three species of monkeys. The mandatory teratogenic tests on potential medicines instituted by the regulatory authorities as a result of the thalidomide disaster prevented a similar tragedy with the oral acne treatment retinoin. This medicine, because of its efficacy, was marketed despite its known teratogenicity in laboratory animals. Since it was labelled as having a confirmed teratogenic risk, only a few cases of fetal abnormality occurred as a result of inadvertent exposure.

The claim that isoprenaline is well tolerated in cats at doses 175 times greater than those considered safe for humans is also incorrect. The human data were gathered from patients taking isoprenaline during the hypoxic conditions of an asthma attack; if cats are rendered similarly hypoxic they also become sensitive to the cardiotoxic actions of isoprenaline.

The antivivisection literature is replete with emotive propaganda and exaggerated claims of "bad science." A definitive examination of the literature, however, generally exposes criticisms as spurious. Their perpetuation in books such as *Vivisection or Science* does nothing for the ethical debate.

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1 MacDonald R. Vivisection or science? An investigation into testing drugs and safeguarding health [book review]. *BMJ* 2001;322:115. (13 January.)

Wyeth responds to news story on oral contraceptives and DVT

EDITOR—In a News article, van Heteren reports on a Dutch radio broadcast about the issue of deep venous thrombosis and third generation oral contraceptives.¹

There is no truth in the allegation made in the broadcast that Wyeth suppressed the results of a research study. The study report was provided to the European Agency for the Evaluation of Medicinal Products in April 2000, and to other regulatory authorities. To repeat this allegation, and particularly to give it prominence in the title of the article, is irresponsible; this is a serious and unresolved scientific debate.

It is important to determine why there are reported differences between various

studies carried out on the United Kingdom general practice research database. As we have made clear in past rapid responses to the *BMJ*, to help resolve this issue Wyeth has repeatedly requested independent scientific review of studies of combined oral contraceptives using the general practice research database.²

We reject absolutely the reported assertion by Dr Alexander Walker, an epidemiologist at Harvard School of Public Health in the United States, that the differences in results are due to the source of funding. In our opinion it is the quality of the study, not whether it is industry sponsored or "independent," which should be the most important criterion for reviewers.

Many research studies are not submitted for publication. The study in question added nothing to scientific knowledge on the subject, and the decision was taken quite properly not to submit it for publication.

The study was not designed to look at deep venous thrombosis as a primary end point. In addition, it had major design and implementation errors—including that the definition of current users allowed for the possibility that women could have stopped treatment and still be considered a current user; cases and controls were not matched by practice, which increases the possibility of prescriber bias; and patients with arterial events (for example, arterial retinal events) were included in the group with deep venous thrombosis as well as patients who had recently delivered a baby or had surgery (both these factors are predisposing factors for venous thrombosis).

Wyeth remains committed to the resolution of this important public health issue through rigorous scientific evaluation.

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1 Van Heteren G. Wyeth suppresses research on the pill, programme claims. *BMJ* 2001;322:571. (10 March.)

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C reactive protein and acute phase of ischaemic stroke

EDITOR—Higher C reactive protein concentrations indicate increased risk of coronary and cerebrovascular events in otherwise healthy individuals¹ and a worse prognosis in myocardial infarction² and ischaemic stroke.³ According to Pepys and Berger, the available data support its potential role as a marker of cardiovascular risk.⁴ To be of clinical use, however, the protein must have an independent prognostic value over and above that of the data already routinely available.

In patients with acute myocardial infarction or ischaemic stroke the extent of necrosis is the main but not the only determinant of prognosis. Age and vascular comorbidity are not necessarily related to infarct size but are nevertheless important predictors of

prognosis. The reasons for a variable response to the necrotic insult are probably multiple and require a clear understanding as they may represent independent additional determinants of prognosis.

I looked again at data that colleagues and I obtained in a cohort of patients after ischaemic stroke.³ The C reactive protein concentrations increased (≥ 5 mg/l) in about three quarters of patients within 24 hours after ischaemic stroke, and higher values were significantly associated with large infarct size (60% (n=87/146) v 26% (n=12/47); $P < 0.0001$, χ^2 test) and worse outcome (36% (n=52) v 9% (n=4); $P = 0.0008$, log rank test). Smaller increases were reported in patients with small infarcts (median 8 mg/l (25th to 75th centile 3.8 to 26.3 mg/l) v 18 mg/l (10 to 35 mg/l); $P = 0.0002$, Mann-Whitney U test) and deep infarcts (8 mg/l (3 to 26 mg/l) v 19 mg/l (10 to 46 mg/l); $P < 0.0001$).

The strong association between infarct size and increased C reactive protein concentrations may result from accurate quantification of cerebral infarction by computed tomography and from a variable intensity of the acute phase response to inflammatory stimuli (in this case, the extent of cerebral infarction). This possibility is suggested by the observation that 24 hour concentrations were much higher in patients with previous raised concentrations.⁵

If the intensity of the acute phase response was not proportional to the intensity of the inflammatory stimulus, the variable increase in the C reactive protein concentration might not just be a consequence of late recanalisation or persistent occlusion of the infarct related artery. Thus the prognostic importance of the 24 hour concentration may be related partly to the extent of the necrosis and partly to the unknown individual determinants of the intensity of the acute phase response. C reactive protein might indicate the inflammatory status during the acute phase of ischaemic stroke and might aid in current challenges posed in secondary prevention.

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Job titles displayed in the geriatric medicine and medicine sections of the *BMJ*'s classified section, May-October 2000

Departmental title	No (%) of entries (n=478)	Departmental title	No (%) of entries (n=478)
Medicine for the elderly	116 (24)	Integrated medicine for the elderly	2 (0.4)
Geriatric medicine	100 (21)	Special responsibility for the elderly	2 (0.4)
Care of the elderly	96 (20)	Age related medicine	2 (0.4)
Elderly medicine	48 (10)	Adult medicine	2 (0.4)
Elderly care	31 (6)	Care of older people	2 (0.4)
Integrated medicine	20 (4)	Care of the elderly medicine	2 (0.4)
Elderly care medicine	15 (3)	Medical services for elderly people	2 (0.4)
Geriatrics	13 (3)	Medical services for older people	2 (0.4)
Elderly services	5 (1)	Elderly	2 (0.4)
Health care of the elderly	4 (1)	Medical health care of the elderly	1 (0.2)
Health care of older people	4 (1)	Integrated general medicine	1 (0.2)
Medicine for elderly people	3 (1)	Medicine of the elderly	1 (0.2)

What's in a name?

To be medicine for the elderly, or not to be

EDITOR—The specialty of geriatric medicine has not settled on a name, so I was interested to find out which name was the most popular. Additionally, I want to make a case for the use of a single name.

The "geriatric medicine" and "medicine" subsections of the *BMJ*'s classified jobs section were surveyed for six months (May to October 2000 inclusive). The job title displayed in the heading or departmental title for each post was recorded. Jobs in all grades were recorded, providing the post had a "geriatric" component.

Altogether 478 posts in "geriatric medicine" were advertised in 24 issues. The table shows the frequency with which each job title was cited. Commonest was "medicine for the elderly" (116 advertisements; 24%), then "geriatric medicine" (100; 21%), and "care of the elderly" (96; 20%). The words "medicine" or "medical" were used in 317 entries (66%).

The word "geriatrics" was coined by Nascher in 1909 from the Greek *geros*, meaning old man, and *iatrikos*, meaning "pertaining to a physician" (from *iatria*: cure).¹ But geriatrics has not settled on a generic name for itself like similar specialties that combine titles, such as paediatrics or orthopaedics, perhaps because the term is thought to be stigmatising by many patients, the public, and some medical staff.

Having multiple titles for a single specialty implies impermanence and uncertainty, and it could increase confusion as to the function of the specialty. The *BMJ* and royal colleges have always called it "geriatric medicine."

I propose that departments should follow this established lead, but we must recognise that there are simply too many barriers to the universal adoption of the term "geriatric medicine." I believe that the English version of "geriatrics"—that is, "medicine for the elderly"—would be less troubling to the non-geriatrician, as well as being a term already included in two thirds of departmental names.

The *National Service Framework for Older People* requires that elderly people be treated

with equality²; our specialty needs a single title that can be used when bidding for the health resources that older people are due. If the specialty is to continue as a specialty, it needs to establish to which mast it will nail its flag. The late Bernard Isaacs, professor of geriatric medicine at Birmingham University, said: "It is better to change the fame of geriatrics, than the name," but it is more realistic for us all to practise medicine for the elderly.³

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Tautology, or not tautology

EDITOR—Am I the only person to be irritated by the term "coronary heart disease," which graces the title of our national service framework and has become increasingly accepted in medical literature?¹

No doubt it took a working committee many hours at great expense to coin the term, but surely coronary artery disease, ischaemic heart disease, coronary disease, or heart disease would be more appropriate? If tautology has become an accepted product of medical spin can we look forward to using pulmonary lung function tests to assess asthma or dyspepsia guidelines for the gastric stomach?

Are there any tsars out there who can throw light on this issue?

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- 1 Department of Health. *National service framework for coronary heart disease*. London: DoH, 2000.



Rapid responses

Correspondence submitted electronically
is available on our website